SNUR
40 CFR
721.7250



DCN: 50-891003208

[redacted]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

| | | |
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| In the matter of: | ) | Premanufacture Notice |
| | ) | Number: |
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| | ) | |
| | ) | |
| | ) | |
| [redacted] | ) | P-89-632 |
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Consent Order and Determinations Supporting Consent Order

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## I. INTRODUCTION

Under the authority of §5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notice ("PMN") P-89-632 submitted by [redacted] ("the Company"), to take effect upon expiration of the PMN review period.

Under §15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of §5 or any order issued under §5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to §16, and to specific enforcement and seizure pursuant to §17.

## II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for this PMN substance requires the Company to: (a) provide personal protective equipment to its workers to prevent dermal exposure; (b) provide respirators to its workers to prevent inhalation exposure; (c) label the PMN substance and provide Material Safety Data Sheets ("MSDS") and worker training provisions of the Hazard Communication Program; (d) distribute the PMN substance only to a person who agrees to comply with the same worker exposure and environmental release restrictions required in this Consent Order; (e) comply with the Release to Water provisions; (f) maintain certain records;

(g) submit to EPA certain toxicity testing at least 14 weeks before manufacturing or importing a total of [redacted] kilograms of the PMN substance.

## III. CONTENTS OF PMN

Confidential Business Information Claims (Bracketed in the Preamble and Order): submitter identity, production volume, process information, portions of a mixture.

Chemical Identity:

1,3-propanediamine, N,N''-1,2-ethanediylbis-, polymer with 2,4,6-trichloro-1,3,5-triazine, reaction products with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine.

Use: light stabilizer for thermoplastics.

Maximum 12-Month Production Volume: [redacted]

Test Data Submitted with PMN:

1. Acute Toxicity Study - rat oral LD50 >3.2 g/kg
2. Dermal Irritation Study - nonirritating to rabbit skin at a concentration of 0.5 g
3. Eye Irritation Study - corrosive to rabbit eyes at a concentration of 0.1 g
4. Ames Assay - negative in the absence and presence of metabolic activation up to a concentration of 100 ug/plate

## IV. EPA'S ASSESSMENT OF RISK

Health Effects Summary:

Concerns: Health concerns include immunotoxicity; effects on the liver, gastrointestinal tract, and blood; reproductive system toxicity; and severe eye irritation.

Basis: The concern for severe eye irritation is based on data submitted with the PMN. Concerns for immunotoxicity, effects on the liver, gastrointestinal tract, and blood, and reproductive system effects are based on hindered amine analogs.

Absorption: Absorption is expected to be poor via the dermal route of exposure. A substantial fraction of the PMN substance available via inhalation exposure is expected to be deposited as a dust in the upper respiratory tract, cleared and swallowed, and thereupon absorbed via the gastrointestinal tract.

Environmental Effects: Concerns have been raised for chronic effects to aquatic organisms and a concern concentration level of 10 ppb was established. Releases of the PMN substance to water are not expected. However, based on the potential for alternative uses and/or alternative means of disposal, the possibility for environmental risk exists.

Exposure Summary:

| | Manufacture | Process/Use |
|---|---|---|
| # Sites | [redacted] | [redacted] |
| Total # Persons | [redacted] | [redacted] |
| # Days/year | [redacted] | [redacted] |
| Amt. Dermal Exp. | 3,900 mg/day | 3,900 mg/day |
| Amt. Inhal. Exp. | 150 mg/day | 150 mg/day |

## V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

A. EPA is unable to determine the potential for immunotoxicity, effects on the liver, blood and gastrointestinal tract, and reproductive toxicity and aquatic toxicity from exposure to the PMN substance. EPA therefore concludes, pursuant to §5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the health and environmental effects of the PMN substance.

B. In light of the potential risk of human health and environmental effects posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance, and the Agency's conclusion that issuing the Order will not result in any significant loss of benefits to society, EPA has concluded, pursuant to §5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health and the environment.

## VI. INFORMATION REQUIRED TO EVALUATE HEALTH EFFECTS

The Order prohibits the Company from exceeding a specified production volume unless the Company submits a 90-day oral toxicity study as described in the Testing section of this Order in accordance with the conditions specified in the Testing

section. If immunotoxicity is seen in the oral toxicity study, more comprehensive testing may be necessary.

Based on the ecotoxicity hazard identified and the potential for environmental risk if the PMN substance were released to water, any person who is manufacturing, importing, processing or using this substance in a manner that will result in release of the substance to water, is required to submit test data sufficient to evaluate the environmental effects of this substance prior to any release to water. The following tests would be required to evaluate environmental effects:

1. Algal acute toxicity test (40 CFR 797.1050)
2. Daphnid chronic toxicity test (40 CFR 797.1330)
3. Fish early life stage toxicity test (40 CFR 1600)

These additional tests are not required in the Order. However, the Order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of information which will more particularly characterize the inherent toxicity of and exposure to the PMN substance.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

# CONSENT ORDER

## I. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

[redacted] ("the Company") is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the chemical substance: 1,3-Propanediamine, N,N''-1,2-ethanediylbis-, polymer with 2,4,6-trichloro-1,3,5-triazine, reaction products with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine ("the PMN substance") in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the health effects of the substance, and the completion of EPA's review of, and regulatory action based on, that information, except under the following conditions:

### TESTING

(a) Information on the PMN substance which reasonably supports the conclusion that the PMN substance presents a substantial risk of injury to health or the environment, and which is required to

be reported pursuant to section 8(e) of TSCA, shall be reported by the Company to EPA in accordance with EPA's section 8(e) policy statement at 43 Federal Register 11110 (March 16, 1978) as amended at 52 Federal Register 20083 (May 29, 1987). Such reports shall also reference the appropriate PMN identification number for this substance and contain a statement that the substance is subject to this Consent Order.

(b) The Company shall notify, in writing, the EPA Laboratory Data Integrity Assurance Division, Office of Compliance Monitoring (EN-342), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study intended to determine the health or environmental effects of the PMN substance, or within 15 days after the effective date of this Order, whichever is later:

1. The date when the study is scheduled to commence;

2. The name and address of the laboratory which will conduct the study; and

3. The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study.

(c) Each study intended to determine the health or environmental effects of the PMN substance must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted at the time the study is

initiated. Before starting to conduct any study, the Company must obtain approval of test protocols from EPA by submitting written protocols. EPA will respond to the Company within 4 weeks of receiving the written protocols. Published test guidelines specified in paragraph (d) (e.g., 40 CFR 797 or 798) provide general guidance for development of test protocols, but are not themselves acceptable protocols.

(d) The Company is prohibited from manufacturing or importing the PMN substance beyond the following aggregate manufacture and import volume ("the production limit"), unless the Company conducts the following study on the PMN substance and submits all final reports and underlying data in accordance with the conditions specified in this Testing section:

| Production Limit | Study | Guideline |
|---|---|---|
| [redacted] | 90-day Oral Toxicity Study (Gavage method using rats. Special emphasis should be placed on the hemotology, lymphoid organ weights (spleen, thymus), and histology, as well as the cellularity of the bone marrow, thymus and spleen. A histo-pathologic examination of the testes and staging of the sperm should also be included. | 40 CFR 798.2650 |

(e) The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit, in triplicate (with an additional sanitized copy,

if confidential information is involved), the final report of each study and all underlying data ("the report and data") to EPA no later than 14 weeks prior to exceeding the applicable production limit. If the Company does not submit the report and data to EPA at least 14 weeks before reaching the applicable production limit, the Company may not exceed the applicable production limit until EPA completes its review of the report and data and notifies the Company, in writing, that the Company may exceed the production limit.

(f) The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture and import the PMN substance beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e)(1) and (2). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substance, only by mutual consent of EPA and the Company.

(h)(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture and import of the PMN substance beyond the applicable production limit.

(2) The Company may continue to manufacture and import the PMN substance beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) The Company may reconduct the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the

Company, in writing, within 4 weeks of receiving the Company's report.

(i)(1) Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture and import of the PMN substance beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture and import the PMN substance beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to conduct or reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with

subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture and import beyond the applicable production limit.

(j) EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that the PMN substance will present an unreasonable risk of injury to human health or the environment despite the terms of this Order. Upon receipt of such a notice, the Company must immediately cease all manufacture, import, processing, distribution, use and disposal of the PMN substance, unless either:

(1) the Company immediately complies with such requirements as EPA's notice specifies concerning manufacture, import, processing, distribution, use and disposal of the PMN substance; or

(2) the Company submits to EPA, within 4 weeks of receiving such notice from EPA, a written report refuting EPA's finding and the Company receives written notice from EPA that the Company may continue to manufacture, import, process, distribute, use and

dispose of the PMN substance. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(k) Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part IV. of this Consent Order.

## PROTECTION IN THE WORKPLACE

(a) During manufacturing, processing, and use of the PMN substance at any site controlled by the Company, the Company must establish a program whereby:

(1) Each person who is reasonably likely to be dermally exposed in the work area to the PMN substance through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance becomes airborne in a form listed in subparagraph (a)(6) of this section, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with 29 CFR 1910.132 and 29 CFR 1910.133.

(2) In addition to the personal protective equipment described in subparagraph (a)(1) of this section, the following items are required:

(i) Chemical goggles or equivalent eye protection.

(3) The Company is able to demonstrate that each item of chemical protective clothing selected, including gloves, provides an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure within the work area by any one or a combination of the following:

(i) Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area.

(ii) Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the PMN substance alone and in likely combination with other chemical substances in the work area.

(4) Each person who is reasonably likely to be exposed by inhalation in the work area to the PMN substance in the form listed in subparagraph (a)(6) of this section, is provided with, and is required to wear, at a minimum, a NIOSH-approved respirator from one of the categories listed in subparagraph (a)(5) of this section, and the respirator is used in accordance with 29 CFR 1910.134 and 30 CFR Part 11.

(5) The following NIOSH-approved respirators meet the minimum requirements for subparagraph (a)(4) of this section:

(i) Category 19C Type C supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a full facepiece.

(ii) Category 19C Type C supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece.

(6) The following forms of airborne chemical substances are listed for subparagraphs (a)(1) and (4) of this section:

(i) Dust.

(ii) Mist.

(b) If the PMN substance is present in the work area only as a mixture, the Company is exempt from the provisions of this section if the concentration of the PMN substance in the mixture does not exceed 1.0 percent or greater by weight or volume, or 0.1 percent or greater by weight or volume if paragraph (g) of the Hazard Communication Program section of this Order identifies

cancer as a potential human health hazard of the PMN substance. This exemption does not apply if the Company has reason to believe that during intended use or processing in the work area, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever is applicable.

## HAZARD COMMUNICATION PROGRAM

(a) Written hazard communication program. The Company shall develop and implement a written hazard communication program for the PMN substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, Material Safety Data Sheets, and other forms of warning material will be satisfied. The Company must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The Company may rely on an existing hazard communication program, including an existing program established under the Occupational Health and Safety Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written program shall include the following:

(1) A list containing the identity of the PMN substance. The list must be maintained in each work area where the PMN substance is known to be present and must use the identity

provided on the MSDS for the substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Company is required either by another Order issued under section 5(e) of TSCA or by 40 CFR Part 721, Subpart E to maintain a list of substances, the lists shall be combined with the list under this subparagraph.

(2) The methods the Company will use to inform employees of the hazards of non-routine tasks involving the PMN substance (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substance contained in unlabeled pipes in their work area.

(3) The methods the Company will use to inform contractors of the presence of the PMN substance in the Company's workplace and of the provisions of this Order if employees of the contractor work in the Company's workplace and are reasonably likely to be exposed to the PMN substance while in the Company's workplace.

(b) Labeling. (1) The Company shall ensure that each container of the substance in the workplace is labeled in accordance with this subparagraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(A) A statement of the health hazards(s) and precautionary measure(s), if any, identified in paragraph (g) of this section or by the Company, for the PMN substance.

(B) The identity by which the PMN substance may be commonly recognized.

(C) A statement of the environmental hazard(s) and precautionary measure(s), if any, identified in paragraph (g) of this section, or by the Company, for the PMN substance.

(D) A statement of exposure and precautionary measure(s), if any, identified in paragraph (g) of this section, or by the Company, for the PMN substance.

(ii) The Company may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Company need not label portable containers into which the PMN substance is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Company shall not remove or deface an existing label on containers of the PMN substance obtained from persons outside the Company unless the container is immediately relabeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Company shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this subparagraph (b)(2).

(i) The label shall, at a minimum, contain the following information:

(A) The information prescribed in subparagraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed.

(4) The label, or alternative forms of warning, shall be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substance in combination with any other substance subject to an Order applicable to the Company issued under section 5(e) of TSCA or identified in 40 CFR Part 721, Subpart E, and/or a substance defined as a "hazardous chemical" under the Occupational Safety and Health Administration

(OSHA) Hazard Communication Standard (29 CFR 1900.1200), the Company may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Company determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Company must seek a determination of equivalency for such alternative control measures pursuant to 40 CFR 721.30 before prescribing them under this subparagraph (b)(5).

(c) Material Safety Data Sheets. (1) The Company must obtain or develop an MSDS for the PMN substance.

(2) The MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the PMN substance under this section, and, if not claimed confidential, the chemical and common name of the PMN substance. If the chemical and common name are claimed confidential, a generic chemical name will be used.

(ii) Physical and chemical characteristics of the substance known to the Company, (e.g., vapor pressure, flash point).

(iii) The physical hazards of the substance known to the Company, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (g) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substance known to the Company.

(vi) The primary routes of exposure to the PMN substance.

(vii) Precautionary measures to control worker exposure and/or environmental release required under the Protection in the Workplace section of this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide substantially the same degree of protection as the identified control measures.

(viii) Any generally applicable precautions for safe handling and use of the PMN substance which are known to the Company, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Company, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Company.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the Company or another responsible party who can provide additional information on the chemical substance and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the Company must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the PMN substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Company may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the Company becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the MSDS within 3 months from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured, imported, processed, or used in the Company's workplace, the Company must add the new information to the MSDS before the PMN substance is reintroduced into the workplace.

(6) The Company must ensure that persons receiving the PMN substance from the Company are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The Company may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Company must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the PMN substance and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee information and training. The Company must ensure that employees are provided with information and training on the PMN substance. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN substance and whenever the PMN substance is introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph shall include:

(i) The requirements of this section.

(ii) Any operations in the work area where the PMN substance is present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and MSDSs required by paragraph (c) of this section.

(2) The training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substance in or from an employee's work area (such as monitoring conducted by the Company, continuous monitoring devices, visual appearance, or odor of the substance when being released).

(ii) The potential human health and environmental hazards of the PMN substance as specified in paragraph (g) of this section.

(iii) The measures employees can take to protect themselves and the environment from the PMN substance, including appropriate hygienic practices and specific procedures the Company has implemented to protect employees and the environment from exposure to the PMN substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Company under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) Low concentrations in mixtures. If the PMN substance is present in the work area only as a mixture, the Company is exempt from the provisions of this section if the concentration of the PMN substance in the mixture does not exceed 1.0 percent or greater by weight or volume, or 0.1 percent or greater by weight or volume if paragraph (g) of this section identifies cancer as a potential human health hazard of the PMN substance. However, this exemption does not apply if the Company has reason to believe that during intended use or processing in the work area, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever is applicable.

(f) Existing hazard communication program. The Company need not take additional actions if existing programs and procedures satisfy the requirements of this section.

(g) Human health, environmental hazard, exposure, and precautionary statements. The following human health and environmental hazard and precautionary statements shall appear on each label as specified in paragraph (b) and the MSDS as specified in paragraph (c) of this section:

(1) Human health hazard statements. This substance may cause:

(i) eye irritation.

(ii) internal organ effects.

(iii) reproductive effects.

(iv) immune system effects.

(2) Human hazard precautionary statements. When using this substance:

(i) avoid eye contact.

(ii) avoid skin contact.

(iii) avoid breathing the substance.

(iv) avoid ingestion.

(v) use respiratory protection.

(vi) use eye protection.

(vii) use skin protection.

(3) Environmental hazard statements. This substance may be:

(i) toxic to aquatic organisms.

(4) Environmental hazard precautionary statements. Notice to users:

(i) do not release to water.

(5) Each human and environmental hazard and precautionary statement prepared pursuant to this section must be followed by the statement: "See the MSDS for details."

**MANUFACTURING**

(a)(1) The Company shall not cause, encourage, or suggest the manufacture or import of the PMN substance by any other person.

(2) The restrictions contained in subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2)

notifies the Company, in writing, on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If EPA so notifies the Company, the restrictions contained in subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) If EPA promulgates a final SNUR for the PMN substance and the restrictions contained in subparagraph (a)(1) expire in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substance of the existence of the SNUR.

## DISTRIBUTION

(a) The Company shall distribute the PMN substance outside the Company only to a person who agrees to:

(1) Not further distribute the PMN substance to any other person until after the PMN substance has been completely bound in the polymer matrix.

(2) Comply with the same worker exposure restrictions, if any, required of the Company in the Protection in the Workplace section of this Order.

(3) Comply with the same environmental release restrictions, if any, required of the Company in the Release to Water sections of this Order.

(4) Not process the PMN substance:

(i) At a site not in that person's control.

(5) Not use the substance:

(i) At a site not under the person's control.

(b) If, at any time after commencing distribution in commerce of the PMN substance, the Company has knowledge that a recipient of the substance has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section, the Company shall cease supplying the substance to that recipient, unless the recipient is in compliance with a SNUR for the PMN substance, or unless the Company is able to document each of the following:

(1) That the Company has within 5 working days notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Company received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (a) of this Distribution section and will comply with those terms.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (b)(2) of this Distribution section, the Company has knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (a)

of this Distribution section, the Company shall cease supplying the PMN substance to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substance to that recipient only upon written notification from the Agency.

(c)(1) The effect of this Distribution section shall expire 75 days after promulgation of a final SNUR for the PMN substance under section 5(a)(2) of TSCA, unless EPA notifies the Company in writing on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If EPA so notifies the Company, the effect of this Distribution section shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(2) If EPA promulgates a final SNUR for the PMN substance and the effect of this Distribution section in accordance with subparagraph (e)(1), the Company shall notify each person to whom it distributes the PMN substance of the existence of the SNUR.

**RELEASE TO WATER**

(a) The Company is prohibited from any predictable or purposeful release of the PMN substance or any waste stream from manufacturing, processing, or use of the substance:

(1) Into the waters of the United States;

## II. RECORDKEEPING

(a) The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Records documenting the manufacture and importation volume of the PMN substance and the corresponding dates of manufacture and import;

(2) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Company directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(3) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required pursuant to the Personal Protective Equipment section of this Order;

(4) Records documenting the determinations required by the Personal Protective Equipment section of this Order that chemical protective clothing is impervious to the PMN substance;

(5) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

(6) Copies of labels required under the Labeling provisions of this Order;

(7) Copies of material safety data sheets required by the Material Safety Data Sheet section of this Order;

(8) Records documenting compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing, Processing, Use, and Distribution sections of this Order;

(9) Records documenting compliance with any applicable disposal requirements under the Disposal section of this Order, including method of disposal, location of disposal sites, dates of disposal, and volume of PMN substance disposed. Where the estimated disposal volume is not known to the Company and is not reasonably ascertainable by the Company, the Company must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements.

## III. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the health or environmental effects of, or human or environmental exposure to, the PMN substance, to

modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

## IV. EFFECT OF CONSENT ORDER

By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, does not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

Date NOV 2 1 1989

Linda J. Fisher
Assistant Administrator
for Pesticides and
Toxic Substances

Date DECEMBER 27, 1989

[redacted]

## ATTACHMENT A - DEFINITIONS

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Company" means the person or persons subject to this Order.

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labelled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance as required under § 721.72(c).

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"PMN substance" means the chemical substance described in the Premanufacture notice or notices submitted by the Company relevant to this Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where a chemical substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.